DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 30, 2015

ASAHI Intecc Co., Ltd.
% Candace Cederman
Senior Regulatory Affairs Consultant
Cardiomed Device Consultants, LLC
5523 Research Park Drive
Suite 205
Baltimore, MD 21228

Re: K150445
Trade/Device Name: ASAHI Peripheral Guide Wires (ASAHI Gladius, ASAHI Halberd, and ASAHI Gaia PV)
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 3, 2015
Received: June 4, 2015

Dear Ms. Cederman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K150445

Device Name
ASAHI Peripheral Guide Wires (ASAHI Gladius, ASAHI Halberd, and ASAHI Gaia PV)

Indications for Use *(Describe)*
This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary
**[as required by 21 CFR 807.92(c)]**

**ASAHI Peripheral Guide Wires**
ASAHI Peripheral Guide Wire ASAHI Gladius
ASAHI Peripheral Guide Wire ASAHI Halberd
ASAHI Peripheral Guide Wire ASAHI Gaia PV

**510(k)** K150445

| | |
|---|---|
| **DATE PREPARED:** | 2/19/2015 |
| **APPLICANT** | ASAHI Intecc Co., Ltd.<br>1703 Wakita-cho, Moriyama-ku<br>Nagoya, Aichi 463-0024, Japan |
| **OFFICIAL CORRESPONDENT** | Yoshi Terai<br>President, CEO<br>ASAHI Intecc USA, Inc.<br>2500 Red Hill Avenue, Suite 210<br>Santa Ana, CA 92705<br>Tel: (949) 756-8252<br>FAX: (949) 756-8165<br>e-mail: ASAHI.ra-fda@ASAHI-intecc.com |
| **TRADE NAME:** | ASAHI Peripheral Guide Wire series<br>• ASAHI Peripheral Guide Wire ASAHI Gladius<br>• ASAHI Peripheral Guide Wire ASAHI Halberd<br>• ASAHI Peripheral Guide Wire ASAHI Gaia PV |
| **DEVICE CLASSIFICATION:** | Class 2 per 21 CFR §870.1330 |
| **CLASSIFICATION NAME:** | Catheter, Guide, Wire |
| **PRODUCT CODE** | DQX- Catheter Guide Wire |
| **PREDICATE DEVICES:** | **Primary Predicates:**<br>ASAHI Regalia XS 1.0 Peripheral Guide Wire (K083146)<br>ASAHI ASTATO 30 Peripheral Guide Wire 10 (K071721)<br>ASAHI ASTATO XS20 Peripheral Guide Wire (K103057)<br>**Reference Devices:**<br>ASAHI PTCA Guide Wire ASAHI Gaia Third (K133865)<br>Abbott Vascular HI-TORQUE IRON MAN Guide Wire (K963702)<br>Boston Scientific V-18 Control Wire Guidewire (K033742)<br>ASAHI CHIKAI (K112979) |

**INTENDED USE/INDICATIONS FOR USE**

This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

**DESCRIPTION:**

The ASAHI Peripheral Guide Wires in this submission have a coil-type distal end or a plastic covered-type distal end. The coil is partly or entirely radiopaque to facilitate selection of the blood vessel and confirmation of the position of the guide wire's distal end by fluoroscopy.

The core shaft surface is coated with Polytetrafluoroethylene (PTFE). About 2cm of the distal end can be shaped. ASAHI INTECC detachable extension wire (hereafter "extension wire") (previously cleared as part of K083145 and K101985} is available to connect with the proximal end of the guide wire with a length of less than 300 cm. The total length of the system after the connection with be 300cm to 400cm. Torque device may be included in the same package.

The ASAHI Peripheral Guide Wires in this submission have an overall length range of 200 to 300 cm and a nominal outer diameter range of 0.36 to 0.45 mm.

**COMPARISON WITH PREDICATE DEVICES:**

Comparisons of the ASAHI Peripheral Guide Wire and predicate devices show that the technological characteristics of the ASAHI Peripheral Guide Wires such as the components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate devices.

The intended use/indications between the Subject Device and its primary predicates are identical. There are specific design features of the Subject device that are similar to the primary predicate but not identical. Additional predicate devices have been used to demonstrate equivalence for these similar features.

| **Name of Device** | **ASAHI Peripheral Guide Wire**<br>• **ASAHI Gladius**<br>• **ASAHI Halberd**<br>• **ASAHI Gaia PV** | • **Regalia XS 1.0**<br>• **ASTATO XS 20**<br>• **ASTATO 30** |
|---|---|---|
| 510(k) | Current Application | K083146<br>K103057<br>K071721 |
| Intended Use and Indications | This product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only. | |
| Sterilization | Provided sterile via Ethylene Oxide to SAL$10^{-6}$ | |
| Shelf Life | 3 Years | |
| Target Body Location | Peripheral | |

| | |
|---|---|
| Outer Distal Hydrophilic coating | Yes |
| Proximal Coating | PTFE |
| Overall Length | 180-300 cm |
| Nominal OD | 0.36-0.45 mm (0.014-0.018inches) |
| Outer Coil Material | Platinum-Nickel Austenitic Stainless Steel (316 SS) |
| Core Wire Material | Austenitic Stainless Steel (304 SS) |

**NON CLINICAL TESTING / PERFORMANCE DATA:**

Non clinical laboratory testing was performed on the ASAHI Peripheral Guide Wire to determine substantial equivalence. The following testing/assessments were performed:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adhesion/Integrity
- Catheter Compatibility

The *in vitro* bench tests demonstrated that the ASAHI Peripheral Guide Wire met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrate that the device functions as intended, and has a safety and effectiveness profile that is similar to the predicate devices.

**BIOCOMPATIBILITY**:

The ASAHI Peripheral Guide Wire was compared to the predicate devices. Based on similarities of the materials used in the subject device to its predicates, the biocompatibility of the ASAHI Peripheral Guide Wire was verified to be the same as those of the predicates.

**CONCLUSION:**

The ASAHI Peripheral Guide Wire has identical intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI Peripheral Guide Wire is substantially equivalent to the predicate devices.